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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,183	11/14/2001	Alan Gewirtz	43826-9	6995

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EXAMINER	
ASHEN, JON BENJAMIN	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/993,183	GEWIRTZ, ALAN	
	Examiner	Art Unit	
	Jon B. Ashen	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *19 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5,7-9,11 and 21-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5,7-9,11 and 21-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application/Amendment/Claims

1. Claims 1, 2, 5, 7-9, 11 and 21-27 are currently are pending in this application. Applicant's response filed 09/19/2005 has been fully considered. Rejections and/or objections not reiterated from the previous office action mailed 5/23/2005 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The Declaration under 37 CFR 1.132 filed 09/19/2005 is insufficient to overcome the rejection of the instant claims under 35 U.S.C. § 102(e) as being anticipated by Fire et al. as set forth in the last Office action. Please see response set forth below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 23-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims are drawn to a method for disrupting gene expression *in vitro* wherein the method further comprises providing an effective amount of "KdsRNA" .... thereby disrupting gene expression of "KitR".

However, the skilled artisan cannot determine the metes and bounds of what is being claimed with this terminology, without assumption, because it cannot be determined, with any particularity from the text of the claim, what is encompasssed by the abbreviations "KdsRNA" or "KitR." Inclusion of the full name of the gene name for KitR would be remedial in this case.

Moreover, claim 23 is drawn to the method of claim 22, further comprising initiating RNAi in a population of the human cells using "KdsRNA." However, the scope of the relationship of claim 23 to claim 22 cannot be determined without assupmtion because the terminology, "further comprises" indicates that the method of claim 23 is the entire method of of claim 22 plus an additional provision of the KdsRNA to initiate RNA interference. However, there is no contemplation, in the specification as filed, of more than a single provision of a double stranded RNA at one time, to cells *in vitro*, and this provision is double stranded c-Kit RNA. It is therefore not clear if the method that is being claimed requires multiple administrations of different double stranded RNAs.

4. Claims 1, 2, 5, 7-9, 11, 21 and 22 remain rejected and claims 23-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record set forth in the Office Action mailed 10/06/2004 and reiterated in the Action mailed 5/23/2005. Claims 23-27 are included in this rejection based on the "further comprising" language, indicating that the method of claim 23 is in addition to and requires the entire method of claim 22.

Response to Arguments

5. Applicant's arguments filed 09/19/05 have been fully considered but they are not persuasive. In regards to the outstanding rejection under 35 U.S.C. § 112 1st paragraph, written description, Applicant has argued (pg. 4) that since the courts have supported a strong presumption that an adequate written description of the claimed invention is present in the specification as filed, that in light of their responses made of record, the skilled artisan would have understood what was meant by an RNA that is homologous to the target gene and that thus Applicant was in possession of the claimed invention. However, despite Applicant's assertion of the court's position, the written description inquiry is fact based and a strong presumption that an adequate written description of the claimed invention is only a presumption, the fact of an adequate written description of what is claimed, such that it can be reasonably determined that Applicant was in possession of what is claimed, is required. Moreover, the fact that the skilled artisan would recognize what is meant by an RNA that is homologous to the target gene is not the basis of the outstanding rejection, but that the skilled artisan would not recognize that Applicant was in possession of a method, commensurate with the breadth of what is now claimed. The disclosure of the specification and the teachings of the prior art, as a whole, fail to provide or point to the structure of an RNA that can have any degree of homology to any target gene, that is commensurate with what is claimed, that will function in a method of inhibiting the expression of any gene, or a representative number of genes within the broad genus of "target genes," by RNA interference, *in vitro*, in any human cell.

Applicant's arguments with regard to the degree of homology for the claimed invention that is inherently disclosed in the examples of the specification, the error rates of RNA polymerases and that the disclosure of the specification provides the upper and lower length limitations of the dsRNA homologous to a target gene were previously presented in the communication filed 03/04/05 and addressed in the Action mailed 05/23/05 (see pgs. 4-5). Applicant states that the specification discloses four general methods of obtaining dsRNA for use in the instantly claimed methods but provides no argument with regard to this statement (pg. 6). Applicant has reiterated, on pg. 6, that the record shows that the examiner has stated that the specification enables the use of RNAi *in vitro* to practice methods of disrupting KitR gene exprssion in human cancer cells. However, Applicant has not presented any argument with regard to this statement and it is noted here that the outstanding rejection is made under 35 U.S.C. § 112 1st paragraph, written description. In particular, the potential enablement of a particular and narrow method within the broad genus of methods now claimed, does not provide adequate written description, commensurate in breadth, with the claimed genus.

Claim Rejections - 35 USC § 112-withdrawn

6. The rejection of claims 1, 5, 7, 9, 11, 21-22 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in view of Applicant's amendment of the instant claims to read on methods *in vitro*.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 2, 5, 7-9, 11, 21-22 are rejected under 35 U.S.C. 102(a) as being anticipated by Kreutzer et al. (WO 00/44895). Kreutzer et al. disclose a method of inhibiting target gene expression in a mammalian cell *in vitro*, (exemplified by the inhibition of target gene expression in a mouse fibroblast cell line on pgs. 17-20), using a short dsRNA (no more than 49 bp in length) homologous to a portion of the target gene in a pharmaceutical composition (pgs. 2. line 26- pg. 5, line 7.) Kreutzer et al. disclose that the medicament of their invention is for use in inhibiting target genes including oncogenes and that their invention makes possible the production of compositions for therapy of genetically determined diseases, including cancer (pg. 4. lines 20-30). Kreutzer et al. disclose that the cells wherein gene expression is inhibited *in vitro* can be human cells (pg. 7, lines 27-29). Therefore, Kreutzer et al. anticipate the instant invention as set forth in claims 1, 2, 5, 7-9, 11, 21-22.

9. Claims 1, 2, 5, 7-9, 11, 21-22 remain rejected under 35 U.S.C. 102(e) as being anticipated by Fire et al. (U.S. Patent 6,506, 559) for the reasons of record as set forth in the Office Action mailed 5/23/05.

Response to Arguments

10. Applicant's arguments filed 09/19/2005, with regard to the outstanding rejection of claims 1, 2, 5, 7-9, 11, 21-22 under 35 U.S.C. 102(e) as being anticipated by Fire et al. (U.S. Patent 6,506, 559) have been fully considered but they are not persuasive. Applicant relies upon the Declaration of Dr. Alan M. Gewirtz to explain why Fire fails to anticipate the instant invention in human cells because Fire taught only the use of dsRNA in invertebrate cells but failed to recognize or address the intracellular defense problems anticipated in mammalian cells and that as shown by Fire's own subsequent work and Padison et al. 2002, neither Fire nor his peers believed that the method would be effective in mammalian cells without substantial additional experimentation to overcome recognized problems (pg. 7). However, the standard for enablement is not if some experimentation is required, or even if a significant amount of experimentation is required, but whether or not the skilled artisan would consider the amount or degree of experimentation required to enable the claimed invention, undue. "Substantial additional experimentation" in light of the disclosure of the Fire patent, which includes a discussion of the art recognized obstacles to using dsRNA to mediate RNAi in mammalian cells, is not considered undue. Moreover, Applicant's contention that Fire

failed to recognize or address the intracellular defense problems anticipated in mammalian cells is countered Applicant's contention that neither Fire nor his peers believed that the method would be effective in mammalian cells without substantial additional experimentation. If neither neither Fire nor his peers believed that the method would be effective in mammalian cells without substantial additional experimentation then Fire must have, at least, recognized problems, for example.

Applicants arguments overall (pgs. 7-11), in regard to the enablement of the Fire patent claims in view of the provided references were considered in the Action mailed 5/23/05 and are not persuasive for the reasons set forth therein (see pgs. 9-10).

Applicant has argued that the claims of the Fire patent cannot be broadly read to include methods of RNAi in a mammalian cell if Fire could not state definitively that gene triggered silencing in vertebrate cells would result from practice of his invention (pg. 8). However, contrary to this argument, the claims of the Fire patent are reasonably interpreted, in light of the disclosure of the specification, to read on the instant methods as claimed. Applicants arguments with regards to what Fire understood are not persuasive because there is no way to determine definitively what Fire "understood" or did not understand. Applicant has argued (pg. 8) that therefore, Applicant's exemplification of RNAi in mammalian cells (human) was contrarty to the wisdom and expectations of other skilled practitioners in the art. However, this argument is not persuasive because an argument of unexpected results is insufficient to overcome a rejection under 35 U.S.C. § 102 based on anticipation. Contrary to Applicant's argument, the claims of the Fire patent anticipate Applicant's invention.

Applicant's arguments drawn to the validity of the Fire patent have been considered but are not persuasive. The Fire et al. reference is an issued patent and the claims are presumed valid. Applicant's arguments that Fire does not expressly claim a method that is effective in mammalian cells (pg. 8) are not persuasive because there is no requirement for Fire to present claims to each and every embodiment that falls within the scope of their invention.

Applicant's states that if Fire, who is one of at least ordinary skill in the art, did not believe in the abilitity to practice his own invention in vertebrates then the Fire patent is not enabling for use by others without undue experimentation. However, contrary to this argument, Applicant has not presented evidence that Fire did not believe in the ability to practice his own invention in vertebrates. Contrary to Applicant's position, as set forth in the Action mailed 5/23/05, Fire provides a review of known information regarding potential difficulties in the application of dsRNA in mammalian cells and provide a reasonable means of overcoming said difficulties; e.g.; by using a controlled level of dsRNA.

Applicant has argued, that Fire, one of ordinary skill in the art, stated a year after his invention, that he did not believe that his inventin could be practiced in mammalian cells (pg. 9) and that while agreeing that an enabling prior art reference need not be a blue print, in the case of the Fire patent, there was a recognized reason why one would not have expected the Fire methods to operate successfully in mammalian cells, that Fire failed to identify the known problem, offered no teaching to overcome this problem and in his own later writings, questioned whether the claimed invention could be

effective in mammalian cells. However, contrary to this, Applicant has not provided evidence that that Fire did not believe that his inventin could be practiced in mammalian cells. Fire's comments, as presented by Applicant in the communication filed 2/01/05, indicate that he believes that RNAi could work in mammalian cells and point out that in order to do so they will most likely require different protocols than the simple ones used in plants and invertebrates and that the problems in mammalian cells can be overcome by a controlled level of dsRNA (thereby identifying the known problem and offering a teaching to overcome this problem, all of which was set forth in the Action mailed 05/23/05). There is no indication in Fire's statements, that he believed that his invention could not be practiced in mammalian cells.

11. In response to the Declaration of Dr. Alan Gewirtz under 37 C.F.R. § 1.132, many of the arguments presented were summarized in the Remarks filed 09/19/05 and have been addressed above. The following remarks address any remaining points in the abovementioned Declaration.

In regards to Applicants arguments with regards to what Fire understood or believed, with regard to the mechanism of RNAi in mammalian cells, or had specifically exemplified within the scope of his invention (sections 6-8), these arguments are not persuasive for the reasons set forth above. Applicant's arguments with regard to the Montgomery et al. reference 1998 (section 10) are not persuasive for the reasons set forth above. Applicant's arguments with regard to Fire et al. (section 11) are not persuasive because there is no requirement for Fire to have understood, in minute

detail, the mechanism's of the PKR response and Fire's comments are reasonably interpreted to indicate that he recognizes the problems in mammalian cells and that they can be overcome by a controlled level of dsRNA (thereby identifying the known problem and offering a teaching to overcome this problem, all of which was set forth in the Action mailed 05/23/05). There is no indication in Fire's statements, that he believed that his invention could not be practiced in mammalian cells. Applicant's arguments, that Fire's post filing statements indicate that he did not believe that his invention could be applied to mammalian cells without substantial additional research (section 13) are addressed above. Applicant's assertion (section 13) that Fire would actually discourage one of skill from attempting to practice the '599 invention in vertebrate cells is countered by Fire's identification the known problem and offering a teaching to overcome this problem, as set forth above.

Applicant's arguments concerning the post filing references of Paddison et al., Wianny et al. Svoboda et al. and Tuschl et al. (sections 14-17) are not persuasive for the reasons of record as set forth in the action mailed 5/23/05. Moreover, Applicant's arguments that the Fire specification does not disclose what was known in the state of the art, which according to Applicant was the knowledge that to practice Fire's invention in mammalian cells one would have to deal with the "expected intracellular defenses" (sections 19-20), are not persuasive because there is no requirement for the Fire specification to disclose what was known in the state of the art. Contrary to Applicant's position, it is not clear that the art did not believe that the Fire method would be effective

in mammalian cells, only that it would require additional experimentation, that was not undue, to practice the method as disclosed and claimed in the '599 patent.

Applicant's arguments drawn to why a non-patent literature reference may or may not have been considered "pioneering" by the state of the art are not persuasive because they do not reflect on the patentability of the instant claims, which is determined in view of all prior art, including patents (section 21). Applicant's arguments, in section 22, about what Fire did or did not specifically exemplify in the '599 patent and what he did or did not believe have been addressed previously in this action. Applicants arguments, with regard to Paddison et al. (sections 22-24) are not persuasive for the reasons set forth above, contrary to Applicant's position, it is not clear that the art did not believe that the Fire method would be effective in mammalian cells, only that it would require additional experimentation, that was not undue, to practice the method as disclosed and claimed in the '599 patent. Applicant's arguments (sections 25-27) with regard to their exemplification of a specific embodiment of the Fire invention are not persuasive because, as set forth above, Applicant's embodiment is anticipated by the Fire invention, as set forth in the disclosure and claims of the Fire patent.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fire et al. as applied to claims 1, 2, 5, 7-9, 11, 21-22 above, and further in view of Gewirtz et al (WO 92/19252).

The instant invention set forth in claims 22 and 23 is reasonably interpreted, in light of the 112 2nd paragraph rejection set forth above, to be drawn to a method for disrupting target gene expression *in vitro* in a human cell comprising providing small interfering RNA guide sequences which are homologous to a portion of a target gene wherein the target gene is c-Kit. Additional dependent claims 24-27 require that the human cells are particular types cells, are malignant, that the interfering RNA comprises part of a pharmaceutical composition and that the pharmaceutical composition is used to treat human disease or disorders.

Fire et al. teach a method for inhibiting expression of a target gene using double stranded RNA to induce RNAi in a cell *in vitro* (Column 26, claim 1) wherein the cell is from an animal (Column 26, claim 6) and the dsRNA has a length of identical nucleotide sequences that may be at least 25, thereby teaching short interfering RNA guide sequences (col. 8, line 5). Fire et al. teach that the cell with the target gene may be derived from or contained in any organism (column 8, line 13-14) and that examples of vertebrate animals include mammals and human (column 8, lines 35-37) and that the cell having the target gene may be "immortalized or transformed, or the like" (column 8, lines 52-55) and that "the present invention could be used for treatment or development of treatments for cancers of any type, including solid tumors, sarcomas and leukemias..." (Column 10, lines 26-28). Fire et al. teach target genes that are

oncogenes (col. 11). Fire et al. teach that lipid mediated carrier transport can be used to introduce nucleic acids to cells (Column 9, lines 55-60). Fire et al. also teach that inhibition of gene expression refers to the absence (or observable decrease) in the level of protein and/or mRNA product from a target gene (Column 6, lines 55-57), thereby indicating disruption of gene function (which is to produce protein). Fire et al. teach that using the methods of their invention, gene disruptions may be used to discover the function of a target gene and to produce disease models in which the target gene is involved in causing or preventing a pathological condition (col. 5, lines 30-37). Fire et al. disclose, that relative to antisense approaches, their invention has advantages in the stability of the material to be delivered (col. 3, line 20). Fire et al. do not teach the nucleotide sequence of the oncogene c-Kit.

Gewirtz et al. teach the antisense inhibition of c-Kit proto-oncogene expression in human cells and that c-kit antisense oligonucleotides are particularly useful against leukemia (Abstract; pg. 15.). Gewirtz et al. disclose that the c-Kit cDNA sequence was known in 1987 and cite Yarden et al.).

It would have been *prima facie* obvious to one of ordinary skill in the art, at the time the instant invention was made, to practice a method of inhibiting the expression of the oncogene c-Kit *in vitro*, in human leukemia cells (as taught by Gewirtz et al.) using a 25 bp double stranded RNA to initiate RNA interference wherein the dsRNA was comprised in pharmaceutical composition (as taught by Fire et al.) because antisense inhibition of c-Kit was taught in the prior art as inhibiting the expression of KitR in human leukemia cells (as taught by Gewirtz et al.), because dsRNA can be used to initiate RNA

interference *in vitro* by targeting oncogenes in human cells including leukemias (as taught by Fire et al.) and because relative to antisense approaches, dsRNA used to inhibit gene expression has advantages in the stability of the material to be delivered (as taught by Fire et al.).

One of ordinary skill in the art would have been motivated to practice a method of inhibiting the expression of the oncogene c-Kit *in vitro* in human leukemia cells (as taught by Gewirtz et al.) using a 25 bp double stranded RNA to initiate RNA interference wherein the dsRNA was comprised in pharmaceutical composition (as taught by Fire et al.) because antisense inhibition of c-Kit was taught in the prior art as inhibiting the expression of KitR in human leukemia cells (as taught by Gewirtz et al.) and because relative to antisense approaches, dsRNA used to inhibit gene expression has advantages in the stability of the material to be delivered (as taught by Fire et al.).

One of ordinary skill in the art would have expected success in practicing a method of inhibiting the expression of the oncogene c-Kit *in vitro* in human leukemia cells (as taught by Gewirtz et al.) using a 25 bp double stranded RNA to initiate RNA interference wherein the dsRNA was comprised in pharmaceutical composition (as taught by Fire et al.) because antisense inhibition of c-Kit was taught in the prior art as inhibiting the expression of KitR in human leukemia cells (as taught by Gewirtz et al.), because Fire et al. teach that dsRNA can be used to initiate RNA interference in human cells and because relative to antisense approaches, dsRNA used to inhibit gene expression has advantages in the stability of the material to be delivered (as taught by Fire et al.).

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim Objections

14. Claims 9, 11, 21 26 and 27 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 9, 11, 21, 26 and 27 are drawn to the method of claims 1 or 22 wherein the dsRNA is part of a pharmaceutical composition that is used to treat human disease or cancer. The dsRNA as claimed, is the same dsRNA required to practice the methods of claim 1 and 22 because it is not structurally or functionally distinguished. The dependent methods, therefore, are the same, because there are no additional steps, only a recitation of intended use.

Conclusion

15. No claims are allowed.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon B. Ashen whose telephone number is 571-272-2913. The examiner can normally be reached on Monday - Friday, 7:30 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 517-272-08110811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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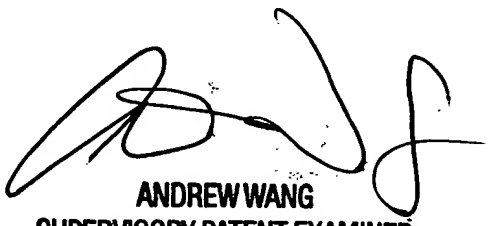

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